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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,754	07/06/2001	Keith D. Allen	R-372	4570

7590 12/24/2002
DELTAGEN, INC.
1003 Hamilton Avenue
Menlo Park, CA 94025

EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/24/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/900,754

Applicant(s)

ALLEN ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16 and 23-33 is/are pending in the application.
- 4a) Of the above claim(s) 16 and 23 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24-27 and 33 is/are allowed.
- 6) ☒ Claim(s) 28-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

This Office Action is a reply to the Amendment filed July 6, 2002 (Paper No. 11) in response to the First Office Action on the Merits mailed May 10, 2002 (Paper No. 8). Claims 1-15 and 17-22 were canceled and claims 24-33 were added in Paper No. 11. Claims 16, 23 and 24-33 are pending in the case. Claims 16 and 23 were withdrawn from consideration in Paper No. 8.

This application contains claims drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Amendment

All rejections set forth in Paper No. 8 are rendered moot by the cancellation of claims 1-15 and 17-22 in Paper No. 11.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28, 29 and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a transgenic mouse wherein the *homozygous* transgenic mouse exhibits one or more of the phenotypes set forth in claim 29, a cell

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or tissue isolated from the transgenic mouse comprising a homozygous disruption in an endogenous mTMT gene and a mouse ES cell transformed with the targeting construct as set forth in claim 32, does not reasonably provide enablement for all progeny produced from the mating of the chimeric mouse according to step (c) in claim 29, for tissue isolated from the transgenic mouse comprising a heterozygous disruption in an endogenous mTMT gene or for all cells transformed with the targeting construct. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Claim 29 is directed to a method of producing a homozygous disruption in an endogenous mTMT gene wherein step (c) mice that are chimeric for disruption of the mTMT gene are bred to produce transgenic mice having a phenotype selected from: decreased body weight; decreased thymus weight; decreased thymus weight to body weight ratio; and increased pre-pulse inhibition. The progeny of step (c) would, however, be heterozygous for disruption of the mTMT gene or non-transgenic. As neither the specification nor the prior art teach that the phenotypes recited in the claim are found in mice comprising heterozygous disruption of the mTMT gene the skilled artisan would not know how to make all transgenic mice produced by breeding the chimeric mouse of step (b) and having the phenotype set forth in the claim. Furthermore, as stated in the previous office action, the only embodiment enabled by the specification within the scope of [the claims] is for a homozygous knockout mouse (Paper No. 8, first full paragraph on page 5). Amending the claim such that it is directed to a method of producing a transgenic mouse comprising a homozygous disruption in an endogenous mTMT

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gene wherein the transgenic mouse comprising *homozygous* disruption of the mTMT gene exhibits the phenotype would overcome this rejection.

Claim 28 encompasses a cell or tissue from a transgenic mouse comprising disruption of an endogenous mTMT. Although the disclosure is sufficiently enabling for claims directed to the heterozygous mouse, as the specification and prior art teach that the heterozygous mouse can be used to produce the homozygous mouse, the disclosure does not set forth a practical utility for cells isolated from the heterozygous mouse. As pointed out in the previous Office Action, “[t]he specification and working examples provide sufficient guidance to practice the invention with only a homozygous, knockout mouse containing two disrupted alleles for the gene that encodes a murine TMT gene...the specification does not teach how to make and use any cell comprising any type of disruption in a tryptase gene as claimed...” (first full paragraph on page 6). The specification and prior art does not set forth a practical use for cells or tissues obtained from the heterozygous mouse; therefore, for reasons of record in Paper No. 8, the disclosure is not enabling for the full scope of claim 28.

Regarding claim 32, as stated in the previous office action, the specification does not teach how to make and use *any* cell comprising any type of disruption in a tryptase gene as claimed (first full paragraph on page 6). The examiner states that the claims are enabled only for a cell derived from the KO mouse (first paragraph on page 3). Therefore, for reasons of record in Paper No. 8 the disclosure is not enabling for the full scope of the claims. Applicant is, however, enabled for a mouse ES cell transformed with the targeting construct of claim 30, which can be used to make the knockout mouse. Therefore, claim 32 would be enabled if the claim were

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amended such that it is limited to a mouse ES cell transformed with the targeting construct of claim 30.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-31 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

Claim 29 is directed to a method of producing a mouse comprising a homozygous disruption in an endogenous mTMT gene; however, the method steps set forth in the claim do not include a step directed to producing a mouse comprising a homozygous disruption of the mTMT gene. Amending the claim to include a step wherein heterozygous mice are selected and bred to produce homozygous mice having the genotype and phenotype set forth in the claim would overcome this rejection. Presently, the methods steps are in conflict with the preamble of the claim.

Claims 30 and 31 are directed to a targeting construct which, when introduced into a murine embryonic stem cell results in a transgenic mouse having a disruption in the endogenous mTMT gene. The claim reads as if the product of an introducing step would be a transgenic mouse. Clearly the targeting construct would not be capable of producing a mouse according to the process recited in the claim. Amending the claim to indicate that the targeting construct can be used in a process of making a transgenic mouse (e.g. the targeting construct when introduced

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into a murine embryonic stem cell, *can be used to make* a transgenic mouse...) would overcome this rejection.

Allowable Subject Matter

Claims 24-27 and 33 are allowed.

Claims 30 and 31 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448.

The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D., can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms

December 19, 2002

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER